



Food and Drug Administration
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Elliquence LLC
Mr. Paul D. Buhrke IV
Quality Assurance/Regulatory Affairs Manager
2455 Grand Avenue
Balwin, New York 11510

October 30, 2015

Re: K142410

Trade/Device Name: Elliquence Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 5, 2015
Received: October 6, 2015

Dear Paul Buhrke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142410

Device Name

Elliquence Electrodes

Indications for Use (Describe)

The Elliquence Electrodes are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. The types of surgery intended are: General surgery, Laparoscopic procedures, Endoscopic procedures, Open abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation, Gynecological coagulation, (except for use in female sterilization), Ear, Nose, Throat coagulation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) Summary
(As Required By 21 CFR 807.92(a))

510K K142410 page 1 of 5

Date Prepared

October 1, 2015

Submitter's Information (807.92(a)(1))

Company Name and Address:

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Establishment Registration for Elliquence, LLC is 3007024186.

Contact Information:

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Device Information (807.92(a)(2))

Trade Name

elliquence Electrodes (encompassing the following product lines: FlexTrode Malleable Electrodes, Depth Gauge FlexTrodes, Clear-Vu Bayonet Electrodes, Empire microIncision Needle Electrodes, MicroFibre Electrode, Standard Electrode Set, Medical Electrode Set, Surg-e Tip Electrode)



Common/Usual Name

Electrosurgical Cutting and Coagulation Device and Accessories

Classification Name

Electrosurgical Cutting and Coagulation Device and Accessories: 21 CFR 878.4400

Class

FDA Classification: Class 2

FDA Product Code: GEI

Predicate Devices (807.92(a)(3))

- PEAK Surgery System (510(k) K082786)
- Valleylab Coated Electrodes (510(k) K962044)
- Davis Bayonet Electrodes (510(k) K964602)

Device Description (807.92(a)(4))

The elligence family of electrodes is a collection of monopolar electrodes which are used in association with an electrosurgical generator, elligence Surgi-Max (K100390). The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site via the active tip of the electrode. The time-varying voltage produced by RF electrical power source yields a predetermined electrosurgical effect, such as tissue cutting or coagulation.

The elligence electrodes are composed of SUS 303 stainless steel, ABS plastic, TEFLON heat shrink tubing, tungsten, brass alloys, and PFA. The basic design of the electrodes consists of an insulated shaft with an uninsulated active tip.

All elligence electrodes share the same materials, design principle, and operating principle, but are available in various shaft and tip configurations in order to satisfy different user preferences. There are eight shaft form “families” which vary in length (1.9 cm to 60 cm), shape (straight, angled, bayonet, and curved), diameter (1/16” and 3/32”), and malleability: (1) FlexTrode Malleable Electrodes, (2) Depth Gauge FlexTodes, (3) Clear-Vu Bayonet Electrodes, (4) Empire microIncision Needle Electrodes, (5) MicroFibre Electrode, (6) Standard Electrode, (7) Medical Electrode, and (8) Surg-e Tip Electrode. The electrode tips are available in three



fundamental configurations:

- (1) loop (round loop, diamond loop, and triangle loop)
- (2) ball
- (3) blade (fine wire, needle, and spatula)

Intended Use (807.92(a)(5))

The Elliquence Electrodes are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. The types of surgery intended are: General surgery, Laparoscopic procedures, Endoscopic procedures, Open abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation, Gynecological coagulation, (except for use in female sterilization), Ear, Nose, Throat coagulation.

Substantial Equivalence Comparison (807.92(a)(6))

The elliquence electrodes device family is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the three chosen predicate devices:

- (1) PEAK Surgery System (510(k) K082786)
- (2) Valleylab Coated Electrodes (510(k) K962044)
- (3) Davis Bayonet Electrodes (510(k) K964602)

An extensive comparison chart is provided within the 510(k) submission.



Non-Clinical Testing (807.92(b)(1))

Bench Tests/Performance Testing

- Hipot Test → Pass
- Drop Test → Pass
- Pull Test → Pass
- Lateral heat spread test → Pass
 - Testing performed on ex vivo bovine tissue. Liver, kidney, and muscle tissue were evaluated with representative samples of the Monopolar Electrodes (ball, loop, spatula). Minimum, default, and maximum settings were performed in triplicate. Measurements of the thermal damage zone were obtained. Results did not raise any new issues of safety or efficacy.
- Bend test → Pass

Biocompatibility

- ISO10993
 - Cytotoxicity → Pass
 - Sensitization → Pass
 - Irritation / intracutaneous reactivity → Pass

Electrical Safety

- IEC 60601-1: Part 1: General requirements for basic safety and essential performance → Pass
- IEC 60601-1-2: Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Electromagnetic Compatibility → Pass
- IEC 60601-2-2: Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories → Pass



Sterility / Shelf Life

- ISO 11135-1: Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices → Meets standard
- ISO 11137-1: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices → Meets standard
- Simulated use test subsequent to accelerated aging → Pass
- Seal integrity testing subsequent to accelerated aging → Pass

Clinical Testing (807.92(b)(2))

Clinical testing was not performed for the elliquence electrodes. The elliquence electrodes do not differ from the predicate devices in fundamental scientific technology or intended use.

Conclusion (807.92(b)(3))

Based upon a comparison of the intended uses, technological characteristics, and performance testing, we have concluded that the subject device is as safe and effective as the predicate devices.